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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,071

Applicant(s)

TOMIKAWA ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 12/06/2004 and 01/18/2005 have been entered.

Status of Claims

2. Claims 13-15 are pending.

It is noted that applicant presents claim 22 as pending claim status "withdrawn". Claim 22 has been previously canceled (see claim version of 05/06/2004, for example). Please, remove claim 22 from list of pending claims.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not disclose limitations regarding use of restriction condition such that an attribute value of each of the elements belonging to

the first point set coincides with an attribute value of the corresponding element belonging to the second point set.

Applicant points at p. 37 which states that "... it is determined .. whether these attributes coincide". Such statement merely describes checking whether attributes coincide, but it does not teach limitation that the attributes do, in fact, coincide.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method of claims 13-15 is merely a mathematical manipulation of data. The claimed method is directed to a method of comparing spatial coordinates of two point sets. A step of merely calculating distance between points, wherein neither the process itself nor the result is statutory, does not render the process statutory. The apparent series of mathematical steps for the data manipulation is equivalent to a mental process. Applicant is reminded that mental processes are not statutory subject matter under 35 USC 101. In the event that the claimed method steps are implemented by a computer, the method steps are not statutory as any computer implemented method must produce a result which is concrete, tangible, and useful (MPEP 2106.IV.B). No physical acts or other "safe harbors" are recited in the claims. A computer-implemented method comprising only steps of data manipulation MAY be statutory when the result produced is concrete, tangible and useful.

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However, the method of claims 13-15 does not produce a concrete, tangible and useful result.

As set forth in MPEP 2106.IV.B.

A process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process. In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

And at MPEP 2106.IV.B.2(b) (ii):

A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory.

The "practical application" toward which the claims are apparently directed is the analysis of a three dimensional structure. The claims recite steps of calculation of distance between elements of two points sets. There is no recited step of determining or indicating a degree of similarity between the structures, or of calculating similarity of the protein to a known structure. The result of the mathematical calculation, per se, is not a concrete, tangible, and useful result as one skilled in the art would not know what the result is intended to indicate.

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5. Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claimed method is directed to a method of comparing three-dimensional coordinates of two sets of three-dimensional coordinates. The claimed method steps result in calculation of a root mean square distance between elements belonging to two point sets. The two point sets, as claimed, are not limited to any particular physical object or structure. Specification describes examples in which a set of elements constituting a molecule is divided into subsets based on the secondary structures, and the subsets are related to each other based on the similarities of spatial position relationships of elements that belong to the subsets; further, specification describes evaluation of similarities of spatial position relationships of a plurality of subsets that are related to one another. See paragraphs [0298]-[0333]. Thus, the sets of three-dimensional coordinates are not limited to originate from two different structures, and the method may represent comparison of different "domains" of the same structure, e.g. of a nucleic acid. The claims therefore encompass comparison of point sets from different areas (domains) of the same molecule. The specification does not disclose a utility for comparing different parts of the same compound or molecule and none is apparent. The claims also encompass comparing sets of points from two different structures, whereupon the method may presumably be used to compare different molecules, specifically proteins. A "use" of the inventive method for comparing different molecules is set forth and exemplified in the specification, paragraphs [0298]-[0333]. However, while the example of the specification provides results of the comparison, there is no disclosure for what

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one skilled in the art would, in fact, use this information for. The specification also asserts, on page 16, that the inventive method may be used to extract motifs. However, an extraction of motifs requires a determination of a degree of similarity between two proteins/sequences/structures. The claims do not recite any step or limitation for determining a degree of similarity. Merely elucidating how far apart elements of compounds are is not an indication that the compounds are, in fact, similar enough to identify the elements as comprising (presumably conserved) motifs, or are different, such that the elements can be eliminated from further consideration/comparison. The claims do not identify any particular compounds for comparison. Even where the claims encompass proteins, in the absence of any knowledge of identity, function, etc., of the proteins being compared, nor any determination of a degree of similarity between two proteins, the claims do not provide an "immediately useful" result. According to MPEP 2107.01 and as set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ 2d 1600), a "useful invention" is one wherein the "usefulness" is "immediately apparent to those familiar with the technological field of the invention. As further set forth in MPEP 2107.01, a "use" to do further research, or assaying for or identifying a compound which itself has no, or an unknown utility, is not considered a "substantial utility" under 35 USC 101. As the structures being "assayed" are unknown/not identified in the claim, their utility is unknown. More information and/or further research would be required by one skilled in the art to know what to do/how to use the results of the claimed method and apparatus, as set forth above

6. Claims 13-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102.

7. Claims 13-15 remain rejected under 35 U.S.C. 102(b) as anticipated by US 4,853,871 or Holak et al. or Flaherty et al. or Mosimann et al. The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that the referenced prior art does not teach description of the “restriction condition”. The “restriction condition” added in the amended claim 13 is coincidence of attribute values of first and second sets. However, first, the claim language does not require coincidence of all points of the data sets; rather, according to step b) of claim 13, from among all candidates for correspondence, it generates correspondences for those points attribute values of which coincide. That is exactly what all methods teaching comparison of two three dimensional structures do – superimposing three dimensional structures, identifying coordinates that coincide and determining the deviations for other coordinates by calculating rmsd’s. Second, the term “coincide” that is now used in claim 13 is not explained in the specification. Dictionaries provide both broad and restricted meaning of the term. Thus, Dictionary.com

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(<http://dictionary.reference.com/search?q=coincide>) offers the following meanings of the term:

1. To occupy the same relative position or the same area in space.
2. To correspond exactly; be identical.

From the point of view of the broadest interpretation of the term - occupying the same area in space (rather than more limited meaning of corresponding exactly) – every reference does place the structures being compared in the same space and then identify correspondence between the elements of the structures..

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 13-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16,17 of co-pending application 09/909809 or claims 5-11,24 of co-pending application 09/910054.

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The referenced claims of both applications are drawn to methods of analyzing three-dimensional structures including steps of dividing points, generating correspondences and calculating rmsd, as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER